

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Medi-Physics, Inc. d/b/a GE Healthcare 4380 Brockton SE, Ste. 3 Kentwood, Michigan 49512 REPORT NUMBER(S) 2009-001		2. NRC/REGIONAL OFFICE Region III U.S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532-4351	
3. DOCKET NUMBER(S) 030-34090		4. LICENSEE NUMBER(S) 21-26707-01MD	5. DATE(S) OF INSPECTION October 28, 2009

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

_____ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

- 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Licensee's Statement of Corrective Actions for Item 4, above.

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Geoffrey M. Warren		10/28/09

228

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE Medi-Physics, Inc. d/b/a GE Healthcare REPORT NUMBER(S) 2009-001		2. NRC/REGIONAL OFFICE NRC Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532-4351	
3. DOCKET NUMBER(S) 030-34090		4. LICENSE NUMBER(S) 21-26707-01MD	5. DATE(S) OF INSPECTION Oct. 28, 2009
6. INSPECTION PROCEDURES USED 87127		7. INSPECTION FOCUS AREAS 03.01 – 03.07	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT Jonathan Winter, R.Ph, RSO	4. TELEPHONE NUMBER 616-554-5717
-----------------------------	------------------	---	-------------------------------------

Main Office Inspection Next Inspection Date: Oct. 2011

Field Office _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This facility was a nuclear pharmacy located in Kentwood, Michigan. Licensee staff consisted of three pharmacists, two technologists, and eleven drivers. The pharmacy manufactured and distributed approximately 230 unit doses and bulk technetium vials daily Monday through Friday to 19 regular customers in western Michigan, mostly in the Grand Rapids area. Most of the diagnostic unit doses were technetium-99m compounds, but licensee personnel also prepared occasional doses of gallium-67 and thallium-201. Licensee operated from around 1:00 AM until 4:00 PM on weekdays and occasional hours on weekends. The first run started at 2:00 AM and went out by 4:00 AM; the second run started about 7:00 AM and left by around 8:30 AM; and other runs were performed as needed throughout the day. The pharmacy received two molybdenum-99/technetium-99m generators weekly. Licensee compounded iodine capsules and received and redistributed xenon-133 vials and iodine-125 capsules. Corporate office personnel performed audits annually to review performance at this facility.

Performance Observations

During this inspection, the inspector observed generator elution, molybdenum assays, kit preparation and tracking, dose preparation, outgoing package surveys and wipes, wipe counting, shipping paper preparation, vehicle packing, shipping paper placement, package return surveys and wipes, returned waste disposal, lab surveys, spot decontamination and resurvey, and survey meter QC. Licensee personnel demonstrated iodine-131 capsule compounding, dose calibrator constancy checks, and package receipt surveys and wipes, and described dose calibrator linearity, accuracy, and geometry tests, spill procedures, waste tracking and disposal, air monitoring, bioassay procedures, and response to vehicular accidents. No issues were identified with these practices. The inspector reviewed licensee audit reports and documentation. Interviews with licensee staff indicated adequate knowledge of radiation safety procedures and concepts. Surveys indicated radiation levels appropriate for restricted and unrestricted areas.